CHAPTER 7. ZONATION

7.1 Introduction

This chapter will discuss how surveillance data can be used to establish zones based on the presence or absence of pathogens in areas of the United States.

For facilities engaged in the culture and subsequent movement of live aquatic animals, the ability to certify those animals as free from certain diseases can increase market access. For example many salmonid egg producers, mollusk producers, and shrimp broodstock producers already have disease prevention, control, and management strategies in place in order to declare themselves as "disease-free" from specific pathogens. Consequently, the relevant State and/or Federal competent authorities are able to issue health certificates that provide opportunities for interstate and international trade.

A number of factors affect the distribution of an aquatic pathogen in a geographical area. Typically, a country's borders do not scientifically reflect that distribution. Some factors which influence the distribution of pathogens include hydrological conditions, presence of susceptible species, ecosystem factors, facility or compartment biosecurity, pathogen management in wild and cultured stocks, and historical movement of live aquatic animals within the country or zone in question.

For example, in the marine environment in both the Pacific Northwest and the Atlantic Maritime area, water, fish, and other mobile organisms and fomites move without restriction back and forth between the waters of the United States and Canada. It is clear that a pathogen present in the open ocean on one side of the border would also eventually be found on the other side. This situation is illustrated in the case of infectious salmon anemia (ISA) in the Atlantic Maritime region, where it was first observed in New Brunswick and subsequently in Maine. Though infected live salmon may not have been purposefully moved across the borders, water currents or other fomites could have easily transported the virus. On the other hand, ISA has never been detected in the Pacific Northwest. Due to the separation of the Atlantic and Pacific regions of North America, and procedures to restrict the movement of ISA-infected fish between the two areas, it is unlikely that ISA would be transported to the Pacific Northwest. This example illustrates that a zonal approach better reflects the distribution of ISA rather than a designating both the United States and Canada as entirely positive countries.

7.2. Types of Zones

The OIE Code identifies three types of zones: free zones, surveillance zones, and infected zones. These zones are determined on a pathogen-specific basis. To remain within current scientific knowledge and maintain international norms, standards for identifying and declaring zones should defer to the current edition of the Aquatic Animal Health Code of the OIE.

In general, a free zone can be a country or an area within a country (that can be as small as an individual premises) where no cases of a specific notifiable pathogen has occurred within a specified time frame, and which is within OIE parameters for recommended surveillance programs and levels of prevalence. The establishment of a free zone is contingent upon its separation from infected zones, the prevention of importation of infected animals from infected zones into the free zone, and the separation of the free zone from infected zone by a surveillance zone.

A surveillance zone is a limited area that is free of a specific pathogen but adjacent to or near an area where a notifiable pathogen has been isolated. To maintain a surveillance zone, an active pathogen surveillance program should be conducted, and importations of aquatic animals into that zone should be carefully controlled.

An infected zone is a country, region, or facility positive for the presence of a specific pathogen.

7.3. Commerce of aquatic animals and their products

One rationale for the NAAHP, as described in Chapter 1, is to provide for efficient and safe commerce of aquatic animals and their products. Commerce of live animals always involves some degree of risk of importing diseases. For that reason, a process known as risk analysis should be used to identify and evaluate 1) the potential hazards of importing aquatic animals into the United States and 2) the potential impacts of pathogens that could be introduced into the United States or into regions previously free of the pathogen. Approaching disease status through risk assessment rather than risk avoidance allows commerce in a way that is scientifically supportable.

7.3.1. Risk analysis as a tool to evaluate proposed commerce

This section is not meant to reiterate or duplicate information already available with respect to import risk analysis. Chapters 1.4.1 and 1.4.2 of the 2006 OIE Aquatic Animal Health Code (the Code) describe international standards of risk assessments which the NAAHP could follow. As a signatory to the Agreement on the Application of Sanitary and Phytosanitary Measures, the United States should follow these guidelines. These OIE chapters do not provide the detail by which a risk analysis is conducted, but rather give an outline of the basic steps.

As paraphrased from the Code, import risk analyses (whether qualitative or quantitative) provide an objective and defensible method of assessing the disease risks associated with commerce of aquatic animals and products. Each analysis, in part, considers an evaluation of the competent authorities and zoning and surveillance systems for monitoring aquatic animal health in the exporting country. The objective is to manage risk appropriately to ensure that a balance is achieved between the desire to minimize the likelihood or frequency of disease

incursions, and the desire to import aquatic animal commodities and fulfill international trade obligations. The process should be transparent so that all information, decisions, and scientific data are made available to stakeholders in order to openly and fairly evaluate the process.

Surveillance provides the points of reference for the status of pathogens in zones. These reference points, along with risk analysis data, can then be used to determine if inter- or intrazone movements present acceptable levels of risk to avoid the introduction of pathogens into a previously free zone.

7.3.2. Guidelines for international, intrastate, interstate, interzonal, or intercompartmental movement

This section will suggest general guidelines and procedures for aquatic animal movements during international, intrastate, interstate, interzonal, and intercompartmental commerce. The primary goal is to prevent the introduction or spread of RAADs, recognizing the authorities of the various legal jurisdictions where the transfers occur, and to make transfers as efficient as possible. Guidelines will vary significantly among commodities, and may vary among pathogens for the same commodity.

Guidelines for transfers

1. No live animals or animal products infected with or exposed to a RAAD should be transferred into U.S. territorial waters or outside the immediate boundaries of a facility, except to a biosecure research laboratory or a processing facility that has biosecurity measures in place to prevent viable pathogens from reentering the surrounding environment.

2. The shipping and receiving facilities should maintain records of the lot, number of animals, and date of shipment. These records may need to be made available to the competent authorities in the event of a disease investigation.

3. Populations of animals to be transferred from declared specific pathogen-free zones should be able to move into zones of similar or lesser health status.

7.3.3. Health inspections, certificates, and associated transfer permits

1. An import permit, which has information on the health status of the animals to be moved and is issued by the appropriate regulatory agency(ies), is the legal vehicle by which all international imports should be reviewed and approved.

2. A health certificate issued by the appropriate regulatory agency(ies) is the legal vehicle by which all movements of animals for international, interstate and interzonal commerce should occur.

3. In the absence of Federal interstate regulations for the movement of aquatic species, individual States are free to implement scientifically based aquatic animal health requirements. Whenever possible, regulatory agencies should coordinate and streamline the permit and certification requirements among the various regulatory agencies for interstate or international movements of all aquatic species.

4. The health permits required by State and Federal competent authorities for aquatic animal movements should be searchable online with an electronic application process to improve efficiency.

5. Harmonized guidelines should be adopted by States and Federal agencies regulating imports and interstate movements for the purpose of consistency in management of aquatic pathogens.